

Attorney Docket No. 9536-3

In re: Vance et al.

Application No.: 10/623,930

Filed: July 21, 2003

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REMARKS

Claims 20, 23, and 26 are pending in the application. Claims 20 and 23 are amended herein for clarity and to more particularly define the invention. In addition, withdrawn claim 1 is amended herein. Support for these amendment are found in the language of the original claims and throughout the specification, as set forth below. It is believed that no new matter is added by these amendments and their entry and consideration are respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

I. Recordation of Interview Summary in accordance with M.P.E.P. § 713.04

Applicants wish to express their appreciation to Examiner Kumar and Examiners Grunberg and Mehta for the time and courtesy extended toward inventor, Vicki Bowman Vance and Applicants' representative, Alice Bonnen, during the in-person interview at the United States Patent and Trademark Office on December 7, 2006.

Applicants wish to make of record the Interview Summary prepared and submitted to applicants by Examiner Kumar on December 13, 2006. Applicants concur that this Interview Summary accurately reflects the substance of the interview.

II Rejection under 35 U.S.C. §112.

A. Enablement.

The Action states that claims 20, 23 and 26 stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement. Action, page 2. Specifically, the Action states that the specification does not reasonably provide enablement for a plant cell or plant transformed with any miRNA precursor construct comprising any miRNA sequence. Action, page 3. The Action further alleges that the invention encompasses non-natural miRNA precursors and naturally occurring polycistronic miRNA precursors. Action, page 4. Additionally, the Action alleges that it would have been highly unpredictable at the time the claimed invention was made that any miRNA precursor design comprising any non-native sequence which is complementary to a portion of target sequence of interest would be effectively processed to produce a stable miRNA product and subsequently participate in producing a gene silencing effect when expressed in a plant cell or plant. *Id.* Finally,

the Action alleges that applicants have failed to provide guidance as to how inoperable embodiments can be readily eliminated other than random trial and error. *Id.*

Claim 20 is amended herein to recite a plant stably transformed with an miRNA precursor construct, said miRNA precursor construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a plant miRNA precursor, said precursor having at least one miRNA sequence incorporated into the plant miRNA precursor, wherein said miRNA sequence replaces the miRNA endogenous to said plant miRNA precursor and is complementary to a portion of a first target sequence.

Furthermore, claim 23 is amended to recite a plant cell stably transformed with an miRNA precursor construct, said miRNA precursor construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a plant miRNA precursor, said precursor having at least one miRNA sequence incorporated into the plant miRNA precursor, wherein said miRNA sequence replaces the miRNA endogenous to said plant miRNA precursor and is complementary to a portion of said first target sequence. Support for these amendments can be found throughout the specification, for example, at least on page 9, lines 7-30 and on page 32, lines 6-23.

Thus, as amended herein claims 20, 23, and 26 recite plant miRNA precursors. Plant miRNA precursors occur naturally in plants and can be isolated using techniques that were known in the art at the time of the filing of the application such as those described in Reinhart et al. (*Genes and Development* 16: 1616-1626 (2002)) and Llave et al. (*Plant Cell* 14: 1605-1619 (2002)) (copies provided in applicants' response dated August 10, 2006). Furthermore, plant miRNA precursors have been shown repeatedly to work as described in the present application and in applicants' prior response dated August 10, 2006. In further support of this contention, applicants provide herewith a Declaration under 37 C.F.R. § 1.132 of Dr. Vicki Bowman Vance (hereinafter "the Vance Declaration"; Appendix A), wherein Dr. Vance discusses the making and using of plant miRNA precursors in which an "artificial" or "designer" miRNA that targets a sequence of interest is substituted for the native miRNA in the plant miRNA precursor. Dr. Vance presents evidence showing the successful use of the present invention.

Furthermore, the techniques needed to discriminate between operable and inoperable embodiments were routine in the art at the time of filing the invention. For

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example, the transient agro-infiltration assay, described in the Vance Declaration, is a screen that was known in the art at the time of filing the present application. As Dr. Vance describes, this assay can be used to routinely screen for operable miRNA precursor constructs without any more effort than is normally required in this field. Accordingly, as outlined above and described in the present specification and in the Vance Declaration, the making and using of the miRNA precursors as described in the present invention are routine in the art and were so at the time of filing the present application.

Therefore, applicants respectfully submit that rejection of claims 20, 23 and 26 under 35 U.S.C. §112, first paragraph, has been overcome and respectfully request that it be withdrawn. If this rejection is maintained, applicants request that a detailed explanation be provided including supporting references to the polycistronic and non-natural miRNAs referred to in the Office Action, pages 3-4.

B. Written Description.

The Action states that claims 20, 23, and 26 stand rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Action, page 5. Specifically, the Action alleges that the specification does not have adequate written description for the genus miRNA precursor sequences and the genus of miRNA sequences comprising a sequence complimentary to a target sequence under current written description guidelines. Action, page 6.

As discussed previously, claims 20 and 23 are amended herein to recite plant miRNA precursors. Applicants respectfully submit that the concerns of the Examiner are addressed by this amendment as well as the foregoing discussion and the Vance Declaration and respectfully request withdrawal of the rejection of claims 20, 23, and 26 under 35 U.S.C. § 112, first paragraph.

III. Rejection under 35 U.S.C. §103(a).

The Action states that claims 20, 23, and 26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Llave et al. (Plant Cell 14: 1605-1619 (2002)) in view of Valvekens et al. 85: 5536-5540 (1988)). Action, page 7. Specifically, the Action states that Llave et al. teaches a number of plant miRNA precursors including miRNA 5 or miRNA 35 (also known as miRNA 167). *Id.* The Action further alleges that Llave et al.

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discusses that miRNA precursors are processed to produce miRNA molecules that are involved in regulating gene expression through post-transcriptional gene silencing. *Id.*

As previously discussed, claims 20 and 23 are amended herein to recite an miRNA precursor construct comprising a first promoter that drives expression in a plant cell operably linked to a first nucleotide sequence encoding a plant miRNA precursor, said precursor having at least one miRNA sequence incorporated into the plant miRNA precursor, wherein said miRNA sequence replaces the miRNA endogenous to said plant miRNA precursor and is complementary to a portion of a first target sequence.

Llave et al. fails to teach or suggest a plant miRNA precursor wherein the native or endogenous miRNA is replaced by a miRNA sequence that is complementary to a portion of a first target sequence as taught by the present invention. Furthermore, Valvekens et al. fails to remedy the deficiencies of Llave et al. Valvekens et al. discusses a method of transforming *Arabidopsis thaliana* and does not teach or suggest plant miRNA precursors wherein the native or endogenous miRNA is replaced by a miRNA sequence that is complementary to a portion of a first target sequence as taught by the present invention.

In view of the foregoing, applicants respectfully submit that claims 20, 23 and 26 are patentable over Llave et al. in view of Valvekens et al., and respectfully request that the rejection be withdrawn.

IV. Rejoinder of claims 1-19.

Claims 1-19 as presented herein include all of the recitations of product claims 20, 23 and 26. Thus, if it is determined that the products of claims 20, 23 and 26 are allowable, applicants request review and examination of these method claims in the present application, pursuant to the practice of rejoinder as set forth in section 821.04 of the MPEP. In particular, it is stated therein that if a product claim is elected in a restriction and then found allowable, withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product claim are to be rejoined in the same application.

Conclusion.

The points and concerns raised in the Action having been addressed in full, it is respectfully submitted that this application is in condition for allowance, which action is

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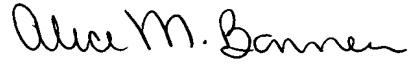
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respectfully requested. Should there be any remaining concerns, the Examiner is encouraged to contact the undersigned attorney to expedite the prosecution of this application.

The Commissioner is authorized to charge Deposit Account No. 50-0220 in the amount of \$790.00 as fee for a large entity for a Request for Continued Examination. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency, or credit any refund to our Deposit Account No. 50-0220.

Respectfully submitted,



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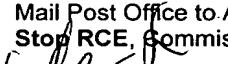
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